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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/658,991	09/09/2003	Ridwan Shabsigh	0575/58075-Z/JPW/AJM/HA	4213

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EXAMINER

KELLY, ROBERT M

ART UNIT	PAPER NUMBER
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1633

MAIL DATE	DELIVERY MODE
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04/03/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/658,991

Applicant(s)

SHABSIGH, RIDWAN

Examiner

ROBERT M. KELLY

Art Unit

1633

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period **will** apply and **will** expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply **will**, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 February 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 9,10 and 12-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9,10,12-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendment and argument of 2/11/08 are entered.

Claims 9, 14, and 18 are amended.

Claims 9, 10, and 12-21 are presently pending and considered.

Claim Rejections - 35 USC § 112 - Enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

While the previous rejections are withdrawn, Claims 9-10 and 12-21 are newly rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of treating vasculogenic erectile dysfunction, in a penis, wherein the subject is suffering from vasculogenic erectile dysfunction, does not reasonably provide enablement for other forms of erectile dysfunction. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Applicants claims encompass treating any form of erectile dysfunction, and such is the whole purpose of the specification in general: treating erectile dysfunction. Moreover, the specification teaches that the methods may be used to treat vasculogenic erectile dysfunction (e.g., p. 28, last paragraph). Hence, it is apparent that Applicant is claiming broader than simply vasculogenic erectile dysfunction. However, the Artisan would naturally find that VEGF is not reasonably predictable to treat any form of erectile dysfunction.

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To wit, it is well known in the Art that VEGF increases vasculogenesis. Moreover, the Art already well-recognized that vasculogenic erectile dysfunction was not the only form erectile dysfunction (e.g., Melman, et al. (1999) Journal of Urology, 161(1): 5-11, e.g., ABSTRACT). Such forms include causes such as smooth muscle tone (e.g., Id.). However, there is no connection that the smooth muscle tone could be treated by vasculogenic affects on the corpora cavernosa. The link simply does not exist in the Art.

Hence, the Artisan would not reasonably predict treatment of the breadth of erectile dysfunctions claimed, because there exist other mechanisms of erectile dysfunction, and Applicant has not shown how these other forms may be treated.

Hence, the Artisan would have to perform the experimentation to find those embodiments outside of vasculogenic erectile dysfunction which would work through the methods. Hence, such experimentation is undue as it amounts to inventing the breadth of Applicant's claimed embodiments for Applicant.

Therefore, the claims are not enabled for their fully claimed scope.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 8-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Levine, et al. (1996) Clinical Urology, 155(4): 1270-73 and U.S. Patent No. 5,652,225 to Isner.

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The Examiner apologizes but a formal copy of the Levine article was unable to be obtained in any form but the full text form, and hence, such copy is supplied instead of the original paper.

Levine teaches that many people suffer from erectile dysfunction due to Peyronie's disease, which includes problems with insufficient vascularization of the corporal tissue (i.e., the corpora cavernosa) (e.g., ABSTRACT). However, Levine does not teach to treat these humans with plasmids encoding with forms of VEGF such as VEGF164/165.

At the time of filing, Isner teaches injecting VEGF encoding nucleic acids for inducing angiogenesis (e.g., CLAIMS), and include the teaching of plasmids encoding VEGF164/165 (e.g., FIGURE 5(b) and EXAMPLE 2).

Hence, at the time of invention it would have been obvious to treat a subject suffering from Peyronies's disease such as that disclosed by Levine because one of the deficiencies is due to insufficient blood flow. Treatment could be accomplished by injection of the corporal tissue with plasmids encoding VEGF164/165. Knowing the affect of VEGF on angiogenesis, the Artisan would do so to treat the disease by increasing vascularization. Moreover, the Artisan would have a reasonable expectation of success, as Isner taught that upon delivery of VEGF that increased angiogenesis would occur.

Conclusion

No claim is allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to ROBERT M. KELLY whose telephone number is (571)272-0729. The examiner can normally be reached on M-F, 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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